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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,211	10/30/2006	Bakulesh Mafatlal Khamar	574152000400	9175

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MORRISON & FOERSTER LLP
1650 TYSONS BOULEVARD
SUITE 400
MCLEAN, VA 22102

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,211	Applicant(s) KHAMAR, BAKULESH MAFATLAL	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22-48.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Response to Office Action, received 11 June 2007, is acknowledged. Claims 22, 28, 29, 30, 31, 32, 34, 44, 45, 46, and 47 have been amended. New claim 48 has been added.
2. Claims 22-48 are pending and under consideration.

Objections Withdrawn

3. The objection to claims 22, 28, 29, 30, 31, 32, 34, 44, 45, 46, and 47 is withdrawn in light of the amendment of the claims.

New Matter

4. The amendment of the specification, filed 11 June 2007, is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- Example 4, page 13 of the marked copy, "dosage of 0.2 ml per week administered...initially followed by a dosage of 0.1 ml per week administered.....both dosages were administered at the interval of one per week". The originally filed specification contained no dosage amounts, no initial/following regimen, and no recitation that the administration was "at the interval of one per week", only "at the interval of one week".
- Example 5, page 14 of the marked copy, "at a dosage of 0.1 ml administered intradermally; the dosage was administered at the interval of one per fortnight". The originally filed specification contained no dosage amount, route of administration, or frequency of administration.

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- Example 6, page 14 of the marked copy, "through nebulizer". The originally filed specification contained no route of administration.
- Example 7, page 15 of the marked copy, "as provided in Example 1D", " at a dosage of 0.1 ml" and "The dosage was administered either through intra-dermal or inhalation route at a frequency of one dosage every fortnight". The originally filed specification contained no dosage, route of administration or frequency of administration. In addition, the originally filed procedure recited "mycobacterium W containing compositions" which is interpreted as being intact, whole mycobacterium W. The newly proposed amendment recites "as provided in Example 1D" which is not intact, whole mycobacterium W, but an "extract" of sonicated mycobacterium W. This change in the composition is considered new matter.
- Example 8, page 15, "a dosage of 0.1 ml), "as provided in Example 1D", and "The dosage was administered intradermally every fortnight for three months". The originally filed specification contained no dosage, route of administration, frequency of administration, or length of treatment. In addition, the originally filed procedure recited "mycobacterium W containing compositions" which is interpreted as being intact, whole mycobacterium W. The newly proposed amendment recites "as provided in Example 1D" which is not intact, whole mycobacterium W, but an "extract" of sonicated mycobacterium W. This change in the composition is considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Rejection Maintained

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5. The rejection of claims 22-47, and now newly added claim 48, under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained for reasons of record.

Applicant argues that the amendment of the specification obviates the rejection.

The examiner has considered applicant's argument, but does not find it persuasive or the reasoning put forth in the original rejection. Because of the new matter issues concerning the proposed amendment of the specification, *supra*, the specification remains as insufficient support for the instant claims.

Conclusion

6. No claims are allowed.

7. Applicant's amendment necessitated the new grounds of rejection of newly added claim 48, as presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)


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272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

August 16, 2007